15A NCAC 02D .0947 MANUFACTURE OF SYNTHESIZED PHARMACEUTICAL PRODUCTS

(a) For the purpose of this Rule, the following definitions shall apply:

(1) "Production equipment exhaust system" means a device for collecting and directing out of the work area fugitive emissions of volatile organic compounds from reactor openings, centrifuge openings, and other vessel openings for the purpose of protecting workers from excessive exposure to volatile organic compounds.

(2) "Synthesized pharmaceutical products manufacturing" means manufacture of pharmaceutical products by chemical synthesis.

(b) This Rule applies to synthesized pharmaceutical products manufacturing facilities.

(c) The owner or operator of a synthesized pharmaceutical products manufacturing facility shall control the emissions of volatile organic compounds from:

(1) reactors, distillation operations, crystallizers, centrifuges, and vacuum dryers that have the potential to emit 15 pounds per day or more of volatile organic compounds with surface condensers that meet the requirements of Paragraph (e) of this Rule or equivalent controls;

(2) air dryers and production equipment exhaust system by reducing emissions of volatile organic compounds:

(A) by 90 percent if they are 330 pounds per day or more; or

(B) to 33 pounds per day if they are less than 330 pounds per day;

(3) storage tanks by:

(A) providing a vapor balance system or equivalent control that is at least 90 percent effective in reducing emissions from truck or railcar deliveries to storage tanks with capacities greater than 2,000 gallons storing volatile organic compounds with a vapor pressure greater than 4.1 pounds per square inch at 68° F; and

(B) installing pressure/vacuum conservation vents, which shall be set at plus or minus 0.8 inches of water unless a more effective control system is used, on all storage tanks that store volatile organic compounds with a vapor pressure greater than 1.5 pounds per square inch at 68°F;

(4) centrifuges containing volatile organic compounds, rotary vacuum filters processing liquid containing volatile organic compounds, and other filters having an exposed liquid surface where the liquid contains volatile organic compounds by enclosing those centrifuges and filters that contain or process volatile organic compounds with a vapor pressure of 0.5 pounds per square inch or more at 68°F; and

(5) in-process tanks by installing covers, which shall remain closed except when production, sampling, maintenance, or inspection procedures require operator access.

(d) The owner or operator of a synthesized pharmaceutical products manufacturing facility shall repair as expeditiously as possible all leaks from which liquid volatile organic compounds can be seen running or dripping. This repair shall take place at least within 15 days after which said leak is discovered, unless the leaking component cannot be repaired before the process is shutdown, in which case the leaking component must be repaired before the process is restarted.

(e) If surface condensers are used to comply with Subparagraph (c)(1) of this Rule, the condenser outlet temperature shall not exceed:

(1) -13°F when condensing volatile organic compounds of vapor pressure greater than 5.8 pounds per square inch at 68°F;

(2) 5°F when condensing volatile organic compounds of vapor pressure greater than 2.9 pounds per square inch at 68°F;

(3) 32°F when condensing volatile organic compounds of vapor pressure greater than 1.5 pounds per square inch at 68°F;

(4) 50°F when condensing volatile organic compounds of vapor pressure greater than 1.0 pounds per square inch at 68°F; or

(5) 77°F when condensing volatile organic compounds of vapor pressure greater than 0.5 pounds per square inch at 68°F.

History Note: *Authority G.S. 143-215.3(a)(1); 143-215.107(a)(5);*
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